



PATENT
Attorney Docket No. 054160-5060

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Tsuneji Suzuki <i>et al.</i>)	
U.S. Application No. 10/049,666)	Group Art Unit: 1615
Filed: February 15, 2002)	Examiner: Gollamudi S. Kishore
Title: Pharmaceutical Agent Comprising a Benzamide Derivative as Active Agent)	Date: <u>December 4, 2006</u>

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Amendment
Randolph Building
401 Dulany Street
Alexandria, VA 22314

DECLARATION UNDER 37 C.F.R. § 1.132

I, the undersigned, Masahiro Sakabe, do hereby declare that:

1. I am a citizen of Japan, residing at 3-8-6-804, Kikukawa Sumida-ku, Tokyo, Japan.
2. I have been awarded a Bachelor's degree in chemistry from the Chiba University.
3. I have been employed by Nihon Schering K. K. since January 1st, 2001 and I am presently a Manager at Nihon Schering K. K.. During my employment at Nihon Schering K. K., I have been engaged in research & development in the area of Pharmaceuticals and in-vitro diagnostics.
4. I am familiar with the specification and pending claims of U.S. Patent Application No. 10/049,666. I have reviewed the Office Action dated March 2, 2006 and the Interview Summary dated May 18, 2006. Regarding the data presented in the tables in the specification, I

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believe that as an artisan skilled in the art of high-performance liquid chromatography (HPLC), the differences between the listed numbers are statistically significant. For example, Table 1 shows that when D-mannitol and compound 1 are mixed together and subjected to the indicated conditions, compound 1 is degraded by 0.21 percent (%) relative to the total amount of compound 1 present in the mixture. This value is comparable to the stability of compound 1 in the absence of any additional component (0.18 or 0.19 depending on the conditions tested). In contrast, when lactose and compound 1 are mixed together and subjected to the indicated conditions, compound 1 is degraded by 0.55 percent (%) or 0.44 % relative to the total amount of compound 1 present in the mixture, depending on the particular conditions tested. Given my level of skill in HPLC chromatography, I believe that the difference between, for example, 0.21 (D-mannitol + compound 1) and 0.55 or 0.44 (lactose + compound 1) is statistically significant in that a conclusion may be drawn regarding the stabilizing effects of D-mannitol on compound 1 and the destabilizing effects of lactose on compound 1.

5. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: November 16, 2006

By: Masahiro Sakabe
(Masahiro Sakabe)